



Europäisches Patentamt  
European Patent Office  
Office européen des brevets



Publication number: **0 515 811 A2**

(12)

## EUROPEAN PATENT APPLICATION

(21) Application number: **92106280.8**

(51) Int. Cl.<sup>5</sup>: **B29C 65/20, A61M 39/00,  
//B29L23:22**

(22) Date of filing: **10.04.92**

(30) Priority: **31.05.91 US 708198**

(43) Date of publication of application:  
**02.12.92 Bulletin 92/49**

(84) Designated Contracting States:  
**AT BE CH DE DK ES FR GB GR IT LI LU MC  
NL PT SE**

(71) Applicant: **DENCO, INC.**  
**501 Silverside Road, Suite 36**  
**Wilmington, DE 19809(US)**

(72) Inventor: **Shaposka, John B.**  
**608 Dean Drive**  
**Wilmington, DE 19808(US)**  
Inventor: **Spencer, Dudley W.**  
**619 Shipley Road**  
**Wilmington, DE 19803(US)**

(74) Representative: **Wagner, Karl H. et al**  
**WAGNER & GEYER Patentanwälte**  
**Gewuerzmuehlstrasse 5 Postfach 22 14 39**  
**W-8000 München 22(DE)**

(54) **Sterile welding of plastic tubes.**

(57) In one practice of the invention plastic tubes are clamped in holders wherein each of the tubes is bent into two sections. Each section has an internal bubble with the bubbles of both sections being aligned with each other. The tubes are cut through the aligned bubbles and one section of one tube is thereafter welded to another section of the other tube. In a further practice of the invention a pair of pivotal holders are provided wherein a tube is mounted in each holder with one section of one tube being out of alignment with a section of the other tube. The tubes are cut and the holders are pivoted to then align the two sections for being welded together.

EP 0 515 811 A2

### Background of Invention

The present invention relates to the sterile and total containment welding techniques for plastic tubes such as fluid filled tubes. There are many applications which require a plastic tube to be connected to another plastic tube. Such applications include, for example, the taking of samples from a bioreactor, the treating of blood, CAPD and other medical applications. Prior patents generally dealing with this subject include U.S. Patents 4,793,880; 4,610,670; 4,369,779; 4,753,697; 4,770,735; 4,897,773; 4,897,138; 4,913,756; and 4,864,101.

It has been found that in the practice of U.S. Patent 4,610,670 an unacceptable level of PVC particles results when the cold seal is reopened after making a weld. The key features in the practice of the '670 patent involve cutting through the flattened areas of the tube and reopening the cold weld. Great care must be taken in using this technology because any residual liquid adversely lowers the hot wafer temperature which was already borderline. When welding through liquid tubes the clamped spacing must be less than one milliliter to be truly flat and expel all of the liquid. As the spacing increases the residual liquid pool gets larger and as a result, the tubes are not touching. When the clamp spacing reaches two millimeters the tube walls in the residual liquid area also are open about two millimeters.

### Summary of Invention

An object of this invention is to provide a process for forming sterile connections with liquid filled tubes which overcomes the above disadvantages.

A further object of this invention is to provide a sterile welding device and method which operates by utilizing pivotal movement of the plastic tube holders for aligning the tube sections to be welded together.

In one practice of this invention a pair of plastic tubes is clamped in a clamping device for each tube wherein each of the tubes is held in a bent condition in two sections. Each of the sections has an internal bubble with the bubbles being aligned. A cut is made through the aligned bubbles and the section of one tube is thereafter welded to a section of the other tube.

In the above practice, the invention may utilize a device wherein the bent tubes are mounted parallel to each other and then shifted to align the two sections which are to be welded together. In a variation of that practice the bent tubes are initially aligned with each other and cuts are made through each of the tubes to result in the bent portions

being removed from the welding area so that the exposed cut tube sections can be moved relatively toward each other for contact and welding.

In a further practice of this invention, a pair of pivotal tube holders are provided with a tube being inserted in each holder in such a manner that the sections to be welded together are out of alignment with each other but then brought into alignment after the cutting operation when the holders are pivoted. In one practice each of the tubes may be mounted in a bent condition in its holder. Alternatively, the tubes may be mounted parallel to each other across both holders.

### The Drawings

Figure 1 is a top plan view partly in section schematically showing a sterile welding system in accordance with one embodiment of this invention;

Figure 2 is a top plan view similar to Figure 1 showing the system in a later stage of operation;

Figure 3 is a top plan view of a further embodiment of this invention in its initial stage of operation;

Figures 4-6 are plan views similar to Figure 3 showing later stages of operation;

Figure 7 is a graph plotting the bubble weight against the gap distance for use in the embodiments of Figures 1-6;

Figure 8 is a top plan view showing a further embodiment of this invention utilizing pivoted holders;

Figures 9-10 are views similar to Figure 8 showing further steps in the operation of the device of Figure 8;

Figures 11-12 are top plan views showing the sequence of operation of yet another embodiment of this invention;

Figures 13-14 are top plan views showing the sequence of operation of still yet another embodiment of this invention;

Figures 15-16 are top plan views showing the sequence of operation of yet another embodiment of this invention; and

Figures 17-18 are top plan views showing the sequence of operation in yet a further embodiment of this invention.

### Detailed Description

The present invention is directed to two different approaches at providing the sterile welding of plastic tubes. In the embodiments shown in Figures 1-6 the cutting of the tubes takes place through aligned bubbles with the sections to be welded together then being brought into contact with each other. In the embodiment of Figures 1-2

the tubes are mounted parallel to each other and the alignment of the sections to be welded together is effected by a shifting operation in a manner well known in the prior art. In the embodiment of Figures 3-6 the bent tubes are initially aligned with each other and the cut portions are removed from the welding area so that contact can be made by a transverse shifting of one or both cut tubes into contact with each other. It is to be understood that the invention can be practiced wherein the tube is cut by the conventional cut/shift method, such as in the '670 patent or by a melt/wipe process such as described in our copending applications, serial nos. 569,855 filed August 20, 1990; 604,979 filed October 29, 1990; and 682,977 filed April 10, 1991, the details of which are incorporated herein by reference thereto. For the sake of simplicity in terminology when reference is made to "cutting", the cutting can be of either type by either physically cutting through the tube or by a melt/wipe operation.

Figure 1 illustrates a sterile welding system 10 which includes a pair of holders 12,14 provided with known suitable clamping arrangements for clamping a pair of tubes 16,20. Each tube is shown as extending across both holders and bent to form two sections 22,24 and 26,28.

As also shown in Figure 1, each section of the bent tubes 16,20 includes a bubble 18. Because the clamping takes place across each holder 12,14 the bubbles 18 result in the unclamped areas between the holders. Thus, all of the bubbles are aligned with each other in the gap between the holders.

As illustrated in Figure 1 a suitable cutting device such as a heated wafer 30 is mounted for movement in the gap between holders 12,14 to cut through the bent tubes with the cutting action taking place through the bubble area. Where the tube is fluid filled, the bubbles are likewise fluid filled otherwise the bubbles would be dry or air filled. The cutting through aligned bubbles differs from our U.S. Patent 4,832,773 where the cutting is through a single air pocket.

After heated wafer 30 has completely cut through both bent tubes 16,20 one of the holding devices such as holding device 12 is shifted in a known manner, as indicated by the arrow, so that tube section 22A becomes aligned with tube section 26A and tube section 24B becomes aligned with tube section 28B. Two stub sections are formed which are not aligned with any other tube sections. These two stub sections comprise the bent portion 22B,24A and the bent portion 26B,28A. All of the various cut sections remain in contact with the heated wafer in the sequence of operation shown in Figure 2. Accordingly, the stub ends become sealed when the wafer 30 is re-

moved whereas the aligned tube sections are disposed toward each other and then move into contact with each other and welded together by a transverse shifting of one holder toward the other in a manner known in the prior art.

Figures 3-6 illustrate a variation of the invention which involves the cutting through the bubble sections of tubes without requiring a shifting of the holders. As shown in Figure 3, device 40 includes a first pair of holders 42,44, each of which has their clamping member and a second pair of holders 46,48 which likewise has its clamping devices for clamping each bent tube 50,52 at two spaced locations thereby creating a series of bubbles 54 at each portion between the respective pairs of holders. Tube 50 is bent to form two portions 56,58 while tube 52 is bent to form two sections 60,62. Each portion in turn includes a section on each side of the bubble designated by the letters A and B.

Device 40 differs from device 10 in that the tubes 50,52 are initially aligned with device 40 whereas the corresponding tubes are parallel to each other with device 10. A wafer 64,66 is disposed for cutting through each bent tube through the bubble section. If desired the wafers 64,66 may comprise separate wafers which move simultaneously or sequentially. Alternatively, the same wafer may move sequentially through each bent tube to effect a cut through the bubble portions. After the cuts have been made the bent portions of tube 50, namely portions 56B and 58A and the bent portions 60A and 62A of tube 52 and their respective holders 44,46 are moved away from the welding area as shown in Figure 4. Where a heated wafer is used the resulting stubs are sealed and may be discarded.

After the stubs and their holders have been removed from the welding area it is necessary that the exposed ends of the remaining tube sections be heated for welding purposes. Where wafers 64,66 are heated the residual heat may be sufficient for these purposes. Otherwise, a heater such as heated wafer 64 may again be brought into contact with the exposed tube sections. This arrangement particularly lends itself to use of the melt/wipe techniques described in our aforementioned patent applications.

Figure 5 illustrates a practice of the invention where the heated wafer 64 is disposed against the exposed ends of cut tube 50. Holder 48 is then laterally shifted so that the exposed ends or faces of tube 52 are also brought into contact with heated wafer 64 as illustrated in Figure 5. Heated wafer 64 is removed after the exposed surfaces have been sufficiently heated and the exposed surfaces are then brought into contact with each other so that a closed tube is created from sections 56A and 60B

with a closed stub being created from sections 58B and 62B, as shown in Figure 6.

Figure 7 illustrates the relationship between the bubble weight of the individual bubbles 18 or 54 and the gap distance between the adjacent clamping devices such as between holders 12 and 14 or holders 42 and 44 and holders 46 and 48.

The invention as practiced with systems 10 and 40 overcomes the disadvantages resulting from prior art such as indicated with respect to U.S. Patent 4,610,670. In the practices of the invention the tubes are not flat and the cooled weld is self-opening. Welding a sterile connection with a controlled liquid pool has a number of advantages. For example, such welding could be used to avoid particulates. Thus, the disadvantage of the prior art would be avoided wherein upon breaking open of the seal particles might be sent into the patient. A further advantage of the invention is that the tubes are self-opening after the weld is made. With a blade or wafer at 750° F and above use can be made of the "Ledenfrost Effect" to create a positive vapor pressure at the weld site to prevent incursion of bacteria. Because of the "Ledenfrost" seal protection a sterile weld can be made without a continuous melt pool as taught by prior art patents 4,369,779 and 4,610,670. Moreover, the technology is applicable to both cut/shift and melt/wipe processes.

Figures 8-18 illustrate various techniques for the welding together of plastic tube sections which are initially out of alignment with each other and then brought into alignment by a pivoting action of the tube holders.

Figures 8-10 illustrate one form of invention wherein the device 70 includes a pair of tube holders 72,74 into which a pair of tubes 76,78 is mounted in a bent manner. If desired the tubes may also be clamped. Bent tube 76 includes a pair of straight sections 80,82 interconnected by a bent section 84. Similarly, tube 78 includes two straight sections 86,88 interconnected by a bent portion 90. Figure 8 illustrates the initial stage of operation wherein the tubes 76,78 are placed in holders 72,74. Figure 9 shows the next sequence of operation wherein a cutting device 92 is moved into cutting contact with the tubes. Device 92 includes a heater 94 and cutting edges 96,98. It is to be understood that the cutting may be a physically cutting through the bent portions of the tubes or may be a melt/wipe type cutting. Cutting member 92 moves in a plane perpendicular to the bent tubes which would be in the Z direction, whereas the holders move in the X-Y directions. During this movement of cutter 92, the bent portions 84,90 are separated from the straight sections and are removed from device 70.

Holders 72,74 are then pivoted about pivot pins

73,73 toward each other as shown in Figure 10 so that section 82 becomes aligned with section 86 while section 80 becomes aligned with section 88. The exposed ends of each section is melted by virtue of the heated cutting device 92 so that upon contact of the respective aligned sections with each other two new tubes are formed, namely a tube resulting from sections 80,88 and a second tube from sections 82,86 with the weld being indicated by the reference numeral 99. If desired, one of the tube holders may be laterally moved toward the other tube holder after the tube holders are aligned when being pivoted around pivot points or axes 73,75 so that the relative lateral movement of the tube holders toward each other assures a firm contact of the heated tube ends. In the preferred practice the pivoting of the holders causes sufficient tube contact without any lateral shifting.

Figures 11-12 show a further device 14 which comprises a pair of tube holders 102,104 pivoted about centrally located pivot pins 106,108. A pair of tubes 110,112 is mounted across the tube holders parallel to each other as shown in Figure 11. A cutting wafer 114 is mounted for movement through the gap between the tube holders 102,104 to separate the individual tubes into four sections 116, 118, 120, 122.

After heated wafer 114 is removed from the cutting area tube holders 102 and 104 are rotated as shown in Figure 12 so that tube section 116 becomes aligned with and contacts tube section 120 and tube sections 122 and 118 are offset and not aligned with any other tube sections. The exposed melted ends of aligned tube sections 118,120 are welded together at weld 124 to form a new tube consisting of tube sections 116 and 120. If desired, although not preferred, the tube holders may be moved laterally relative toward each other to assure firm contact of the aligned tube sections. If desired the exposed cut ends of tube sections 118 and 122 may be sealed so that these tube sections become closed for safety purposes.

Figures 13-14 illustrate a further device 130 having a pair of tube holders 132,134 each of which is pivoted about a respective pivot pin 136,138. A pair of tubes 140,142 is mounted across both holders as illustrated in Figure 13 with each tube consisting of three sections. In this respect, each tube 140 includes straight sections 144,146 joined by bent section 148. Similarly, tube 142 includes straight sections 150,152 joined by bent section 154. A cutting device 156, similar to cutting device 92 is provided which includes a heating element 158 and cutting surfaces 160,162. Cutting device 156 moves in the Z direction perpendicular to the plane of tubes 140,142 to cut the tubes so that bent sections 148 and 154 are then removed and only the straight sections remain. Holders 132

and 134 are then pivoted as illustrated in Figure 14 until each holder abuts against a stop member. As illustrated, stop member 164 is disposed for being contacted by holder 132 while stop member 166 is disposed for being contacted by holder 134. Stop member 166 is adjustable by, for example, including a threaded shaft 168 to vary the position to which holder 134 may be rotated. It is to be understood that the incorporation of stop members may also be utilized in the various other embodiments involving pivoted tube holders.

When holders 132 and 134 are pivoted to the position shown in Figure 14 tube sections 150 and 146 become aligned and are welded together at weld 170. Tube sections 152 and 144 are not aligned with any other tube sections. If desired, the ends 172 and 174 may be sealed.

Figures 15-16 illustrate yet another device 180 which includes a pair of tube holders 182,184 pivoted at pins 186,188. A tube 190,192 is mounted in each respective tube holder in a bent manner. Tube 190 thus has two straight sections 194,196 joined by a bent section 198. Tube 192 has two straight sections 200,202 joined by a bent section 204. A wafer 206 is disposed for cutting through the tubes to remove the bent sections 198, 204 and heat the ends of the exposed straight sections. Holders 182,184 are then pivoted to the position shown in Figure 16 so that tube sections 196 and 200 become aligned while tube sections 194 and 184 become aligned. The pairs of aligned tube sections are joined together by welds 204,206 as shown in Figure 16.

Figures 17-18 illustrate yet another device 210 having a pair of tube holders 212,214 pivoted about pivot pins 216,218. A third tube holder 220 is provided which does not pivot but is longitudinally movable away from the tube holders 212,214. A pair of tubes 222,224 is provided with tube 222 straddling tube holders 212 and 220 while tube 224 straddles tube holders 214 and 220. A wafer 226 moves through the gap created by holder 220 and the pair of holders 212 and 214 to cut the tubes into four sections with tube 222 having straight sections 228 and 230 and with tube 224 having straight sections 232 and 234. Heated wafer 226 moves in a reciprocal direction as illustrated by the arrow.

After the cutting operation tube holder 220 is moved away from tube holders 212 and 214. Thus tube holder 220 carries with it cut sections 230 and 234. Tube holders 212 and 214 are then rotated as indicated by the arrows in Figure 18 so that the remaining straight tube sections 228 and 232 become aligned and are welded together at weld 236.

The various devices shown in Figures 8-18 provide a particularly advantageous manner of welding tube sections together. Tube devices avoid

the two step process of shifting and urging and instead produce a more consistent and reliable weld via the single step of pivoting the clamped tubes into one another.

Device 10 achieves a weld by handling four tube sections without shifting blocks or urging the tubes together although the urging aspect is a non-preferred option.

Device 70 can be used for either bent or straight tubes. A further feature of device 70 is that the cutting means 92 is not between the mounting blocks or holders 72,74.

Device 100 is a slightly different variant that also makes a sterile weld. Device 70 also handles straight-parallel or bent tubes via the cellguard technique. Device 10 operates in a manner that avoids the shift and urge techniques of the prior art. Multiple welds are also possible simply by adding more tube slots and changing the amount of rotation of clamp assemblies or holders 102 or 104. During rotation the clamp assemblies must separate slightly to allow the tube ends to swing by. This motion of pulling the tubes directly away from the wafer 114 also helps to avoid occlusion of the lumen when welding open tubes and is a definite advantage.

Device 130 of Figures 13-14 illustrates the flexibility of the pivoting tube holder technique. In this case, each clamp assembly or tube holder is made to rotate to a different final position allowing a user to weld bent tubes via the cellguard technique of Figures 8-10 straight tubes via changes in the final clamp position, or forming the clamp seals via the misaligned weld technique referred to in our U.S. Patent 4,897,138.

Device 210 is a practical welder using the pivot techniques. The extra clamp or holder 220 which is difficult to implement on other arrangements is very simple with device 210.

The various devices illustrated herein may be used for either dry tubes or tubes containing fluid. In some instances where the tubes contain fluid such as with device 130 a third clamp or other means of limiting fluid volume might be desirable. Similarly, the various devices could be used with tubes which are either round and dry or fluid filled and flattened. With respect to device 100 in order to achieve the desired aligning result one or both of the clamp assemblies must move away from the other during rotation to allow the tube ends to pass.

The provision of an adjustable stop such as stop 166 with device 130 is advantageous in that by suitable adjustment of the stop the welder can become a sealer via the misaligned weld techniques as taught by our earlier Patent 4,897,138.

While the preferred practice is to cut by a heated wafer, the cutting and heating steps may be sequentially performed. The heater for the wafer

may be battery operated, as illustrated in Figures 9 and 13, or may be electrically operated.

It is to be understood that various aspects described with respect to specific embodiments may be used with other embodiments.

The invention may be summarized as follows:

1. A method for the sterile welding of plastic tube sections comprising the steps of bending a pair of tube with a section of each tube bent toward an adjacent section of the same tube to create four sections from the two tubes, mounting each bent tube in a clamped condition across a pair of adjacent but spaced tube holders to create a bubble in each tube section in the gap between the tube holders, cutting through the tube sections at the bubbles by relatively moving a cutting device through the gap, aligning a tube section of one tube with a tube section of the other tube, heating the cut ends of the aligned tube sections, and pressing the aligned ends together to weld the aligned tube sections.

2. The method of 1 wherein said steps of cutting and heating the tube sections are done simultaneously with a heated wafer.

3. The method of 1 wherein the tubes are arranged parallel to each other to provide four aligned bubbles, after the tube sections are cut the one tube section is aligned with the other tube section by a longitudinal shifting of the holders relative to each other, and two stub ends being created from the bent sections with two further stub ends welded to each other as well as the aligned tube sections being welded to each other.

4. The method of 3 wherein the tubes are fluid filled.

5. The method of 1 wherein the bent tubes are mounted to each other by each bent tube being mounted across a separate pair of tube holders, the tubes being cut by a cutting device cutting through pairs of aligned bubbles in each tube, after the two sections are cut the bent portions are removed away from the remaining tube sections, and the remaining tube sections are shifted relatively toward each other to contact the remaining tube sections of one tube with the tube sections of the other tube.

6. The method of 5 wherein the cutting through the two sets of bubbles is done simultaneously by two cutting devices.

7. The method of 5 wherein the cutting through the two sets of bubbles is done sequentially by the same cutting device.

8. The method of 7 wherein the cutting device remains in contact with one of the sets of tube

sections, heating the cutting device, and the other set of tube sections being brought into contact with the heated cutting device to simultaneously heat all four exposed tube sections.

9. The method of 8 wherein two stub ends are welded to each other simultaneously with the aligned tube sections being welded to each other.

10. A device for the sterile welding of plastic tube sections to each other comprising two tube holders, each of said holders having a least one tube receiving area for holding a tube section which is to be welded to the tube section on the other of said holders, said tube receiving area of one of said holders being in non-aligned relationship to said tube receiving area of said other of said holders, each of said holders being pivotally mounted to change the orientation of said holder, cutting means for cutting through a tube mounted on and extending from each of said holders to cut through each of the tubes on said holders, said holders being located with respect to each other a distance whereby the cut ends of the tubes and said tube receiving areas are aligned with each other when said holders are rotated about their pivotal mounting, and means for heating the cut ends of the tubes whereby the tubes are welded together when the cut ends are rotated and are into aligned contact with each other.

11. The device of 10 wherein each of said holders includes two tube receiving areas whereby a bent tube may be mounted to each of said holders, said holders being disposed at an angle to each other when said tube sections are non-aligned, and said holders being pivoted into alignment with each other when said tube sections are welded together.

12. The device of 11 wherein said cutting means comprises a heated cutter having a pair of cutting edges disposed at an angle to each other, and said heated cutter being mounted for movement in a plane perpendicular to the plane of said tubes.

13. The device of 12 wherein both sets of said tube receiving areas are aligned with each other when said tubes are rotated into alignment with each other.

14. The device of 10 wherein each of said holders includes two tube receiving areas, said tube receiving areas of one holder being aligned with corresponding tube receiving areas of the other of said holders prior to the cutting of said tubes whereby each tube would extend across both of said holders, said cutting means being a heated wafer movable through the gaps through said holders while said holders are disposed

parallel to the path of travel of said wafer, and said holders being disposed at an angle to said path of travel when said holders are repositioned to align the tube sections with one of said tube receiving areas on one of said holders being aligned with one of said tube receiving areas on the other of said holders and with the other of said tube receiving areas being unaligned with any other tube receiving area.

15. The device of 10 wherein said holders are disposed at an angle to each other prior to the cutting of said tubes, each of said holders having two tube receiving areas whereby each of two tubes may be mounted across both of said holders with each of the tubes being bent in the space between said holders, and said holders being rotated for the welding step with one of said tube receiving areas on one of said holders aligned with a corresponding tube receiving area on the other of said holders and the remaining tube receiving areas of said holders being unaligned with any other tube receiving areas whereby said remaining tube receiving areas are offset from said aligned tube receiving areas.

16. The device of 15 wherein said cutting means is a heated wafer having a pair of cutting edges at an angle to each other and said heated wafer being mounted for movement in a plane perpendicular to the plane of said holders.

17. The device of 16 including stop members disposed in the path of rotational movement of said holders for stopping the rotational movement of said holders when said holders are disposed with said tube receiving areas aligned with each other.

18. The device of 17 wherein one of said stop members is fixedly mounted and the other of said stop members is adjustably mounted.

19. The device of 10 including stop members disposed for preventing further rotational movement of said holders when said tube receiving areas are aligned with each other.

20. The device of 10 wherein said holders are disposed in side by side parallel relationship prior to the cutting of the tubes, each of said holders having two tube receiving areas whereby a tube may be mounted on each holder in a bent condition with the bent portion of each tube extending beyond its respective holder, and said holders being rotatable for alignment with each other for the welding step.

21. The device of 10 wherein said holders are disposed in side by side parallel relationship with respect to each other, each of said holders having a single of said tube receiving areas, a third holder spaced from and disposed across said two holders, said third holder having two tube receiving areas each of which is aligned

with a tube receiving area from a respective one of said two holders whereby a tube may be disposed in each of said holders and mounted on a respective one of said tube receiving areas in said third holder, said cutting means being a heated wafer which is movable through the space between said third holder and said tube holders, the third holder being movable away from said two holders after the tubes are cut, and said two holders being rotatable into alignment with each other whereby said tube receiving areas of said two holders are thereby aligned.

22. A method for the sterile welding of plastic tube sections of two tubes to each other comprising the steps of mounting a pair of tubes across two pivotally mounted tube holders with the tube sections out of alignment with each other, cutting through the tubes to provide cut ends of the tube sections, rotating the tube holders to dispose the tube sections in line with each other, heating the cut ends of the tube sections, and pressing the tube sections into contact with each other to weld the tube sections together.

23. The method of 22 including disposing said holders at an angle to each other prior to the cutting step, mounting a tube in each of the holders with the tube being in a bent condition having the bent portion extending beyond its holder, the cutting step comprising cutting through the bent ends with a heated wafer to create exposed heated ends from the sections of the tube remaining on the holders, removing the cut bent ends, and rotating the holders into alignment with each other to weld two sets of tube sections on one holder to corresponding tube sections on the other holder.

24. The method of 23 wherein the heated wafer is moved in a direction perpendicular to the plane of the tubes for the cutting step.

25. The method of 22 wherein the holders are initially aligned before the cutting step, mounting two tubes across both holders with the tubes parallel to each other before the cutting step, and rotating the holders after the cutting step so that only one set of tube sections is aligned.

26. The method of 22 including disposing the holders at an angle to each other before the cutting step, mounting two tubes across both holders with each tube being bent in the gap between the holders, the cutting step comprising cutting the tubes at the bent portions of the tubes, removing the cut bent portions, and rotating the holders to dispose one set of sections in line with each other with the other sets of sections being offset from the aligned sections.

27. The method of 26 wherein the cutting step is

done with a heated wafer having spaced cutting edges for simultaneously cutting through two different parts of the tubes, moving the heated wafer in a direction perpendicular to the plane of the tubes during the cutting step, and rotating each holder after the cutting step until the holder contacts a stop member.

28. The method of 22 including disposing the holders in side by side parallel relationships before the cutting step, mounting a tube in each holder in a bent condition with the bent portion extending beyond its holder, cutting the bent portions, removing the cut bent portions, and rotating the holders into alignment with each other to create two sets of tube sections on each holder which are aligned with and welded to corresponding sections on the other holder.

29. The method of 22 including mounting the holders in side by side parallel relationship, mounting a third holder across and spaced from the two holders, mounting each tube across the third holder and one of the respective tube holders, cutting the tubes with a wafer movable in the space between the third holder and the two holders, removing the third holder and the two segments thereon, and rotating the two holders into alignment with each other so that the tube sections on the two holders are aligned and disposed in welding contact with each other.

## Claims

1. A method for the sterile welding of plastic tube sections comprising the steps of bending a pair of tubes with a section of each tube bent toward an adjacent section of the same tube to create four sections from the two tubes, mounting each bent tube in a clamped condition across a pair of adjacent but spaced tube holders to create a bubble in each tube section in the gap between the tube holders, cutting through the tube sections at the bubbles by relatively moving a cutting device through the gap, aligning a tube section of one tube with a tube section of the other tube, heating the cut ends of the aligned tube sections, and pressing the aligned ends together to weld the aligned tube sections.
2. A device for the sterile welding of plastic tube sections to each other comprising two tube holders, each of said holders having a least one tube receiving area for holding a tube section which is to be welded to the tube section on the other of said holders, said tube receiving area of one of said holders being in non-aligned relationship to said tube receiving area of said other of said holders, each of said

holders being pivotally mounted to change the orientation of said holder, cutting means for cutting through a tube mounted on and extending from each of said holders to cut through each of the tubes on said holders, said holders being located with respect to each other a distance whereby the cut ends of the tubes and said tube receiving areas are aligned with each other when said holders are rotated about their pivotal mounting, and means for heating the cut ends of the tubes whereby the tubes are welded together when the cut ends are rotated and are into aligned contact with each other.

3. The device of Claim 2 wherein each of said holders includes two tube receiving areas whereby a bent tube may be mounted to each of said holders, said holders being disposed at an angle to each other when said tube sections are non-aligned, and said holders being pivoted into alignment with each other when said tube sections are welded together.
4. The device of Claim 2 wherein each of said holders includes two tube receiving areas, said tube receiving areas of one holder being aligned with corresponding tube receiving areas of the other of said holders prior to the cutting of said tubes whereby each tube would extend across both of said holders, said cutting means being a heated wafer movable through the gaps through said holders while said holders are disposed parallel to the path of travel of said wafer, and said holders being disposed at an angle to said path of travel when said holders are repositioned to align the tube sections with one of said tube receiving areas on one of said holders being aligned with one of said tube receiving areas on the other of said holders and with the other of said tube receiving areas being unaligned with any other tube receiving area.
5. The device of Claim 2 wherein said holders are disposed at an angle to each other prior to the cutting of said tubes, each of said holders having two tube receiving areas whereby each of two tubes may be mounted across both of said holders with each of the tubes being bent in the space between said holders, and said holders being rotated for the welding step with one of said tube receiving areas on one of said holders aligned with a corresponding tube receiving area on the other of said holders and the remaining tube receiving areas of said holders being unaligned with any other tube receiving areas whereby said remaining tube



receiving areas are offset from said aligned tube receiving areas.

6. The device of Claim 5 including stop members disposed in the path of rotational movement of said holders for stopping the rotational movement of said holders when said holders are disposed with said tube receiving areas aligned with each other. 5
7. The device of Claim 2 including stop members disposed for preventing further rotational movement of said holders when said tube receiving areas are aligned with each other. 10
8. The device of Claim 2 wherein said holders are disposed in side by side parallel relationship prior to the cutting of the tubes, each of said holders having two tube receiving areas whereby a tube may be mounted on each holder in a bent condition with the bent portion of each tube extending beyond its respective holder, and said holders being rotatable for alignment with each other for the welding step. 15
9. The device of Claim 2 wherein said holders are disposed in side by side parallel relationship with respect to each other, each of said holders having a single of said tube receiving areas, a third holder spaced from and disposed across said two holders, said third holder having two tube receiving areas each of which is aligned with a tube receiving area from a respective one of said two holders whereby a tube may be disposed in each of said holders and mounted on a respective one of said tube receiving areas in said third holder, said cutting means being a heated wafer which is movable through the space between said third holder and said tube holders, the third holder being movable away from said two holders after the tubes are cut, and said two holders being rotatable into alignment with each other whereby said tube receiving areas of said two holders are thereby aligned. 20  
25  
30  
35  
40  
45
10. A method for the sterile welding of plastic tube sections of two tubes to each other comprising the steps of mounting a pair of tubes across two pivotally mounted tube holders with the tube sections out of alignment with each other, cutting through the tubes to provide cut ends of the tube sections, rotating the tube holders to dispose the tube sections in line with each other, heating the cut ends of the tube sections, and pressing the tube sections into contact with each other to weld the tube sections together. 50  
55

Fig. 1.

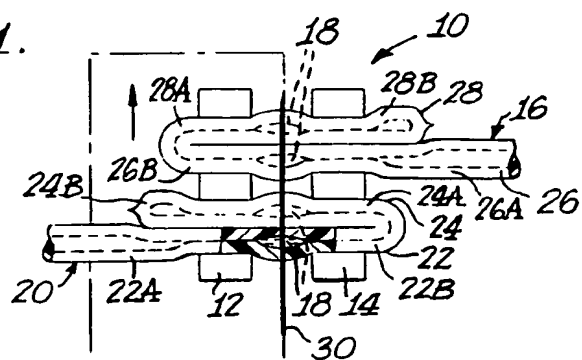


Fig. 2.

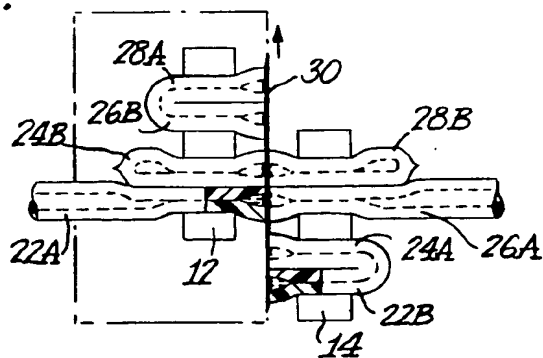
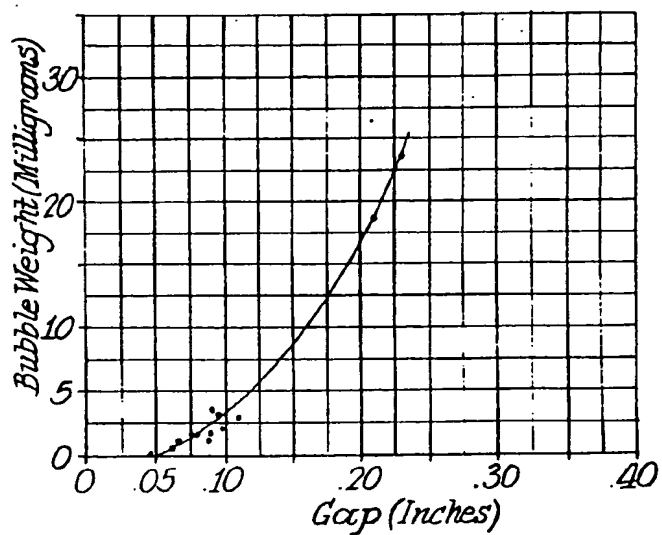
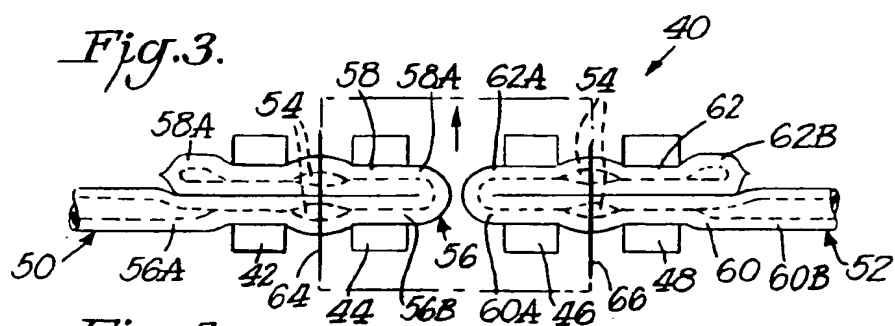


Fig. 7.

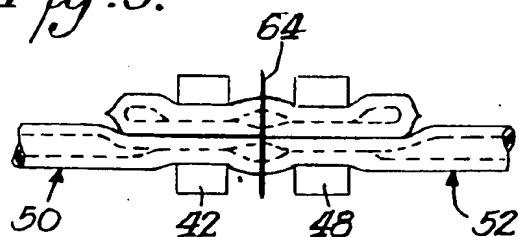




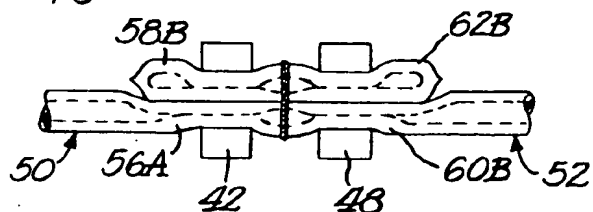
*Fig. 4.*

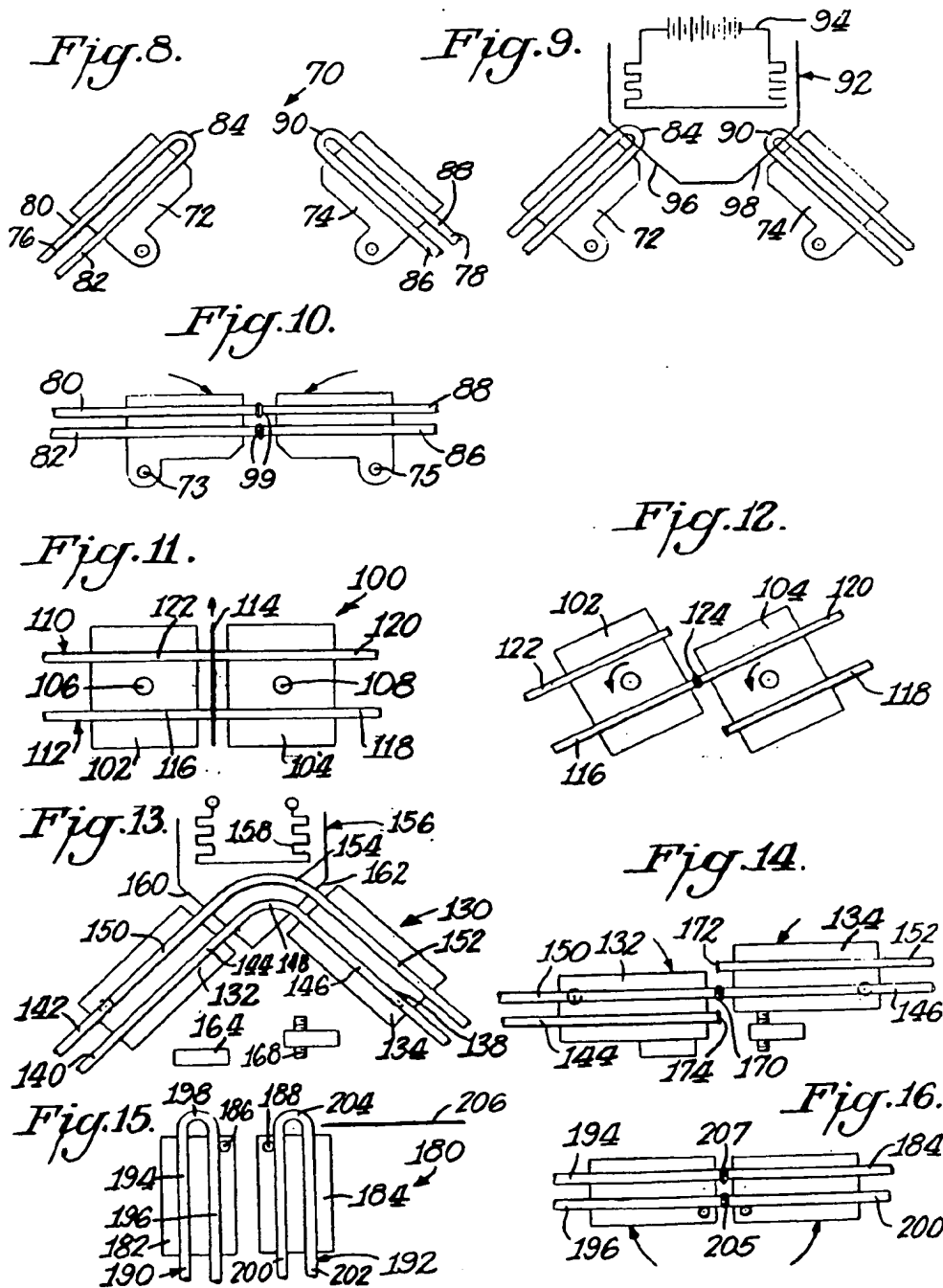


*Fig. 5.*

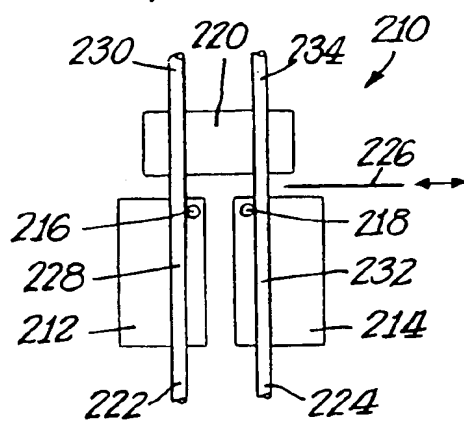


*Fig. 6.*

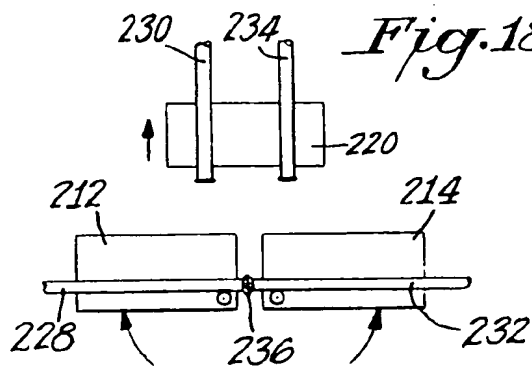




*Fig. 17.*



*Fig. 18.*



**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☒ **BLACK BORDERS**
- ☒ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☒ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☒ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**  
As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.